REMARKS

Claims 64 and 66-89 are pending in the application.

I. THE DOUBLE PATENTING REJECTIONS ARE LEGALLY FLAWED

The examiner rejected application claims for double patenting and for provisional double patenting over commonly owned U.S. patents and patent application. The double patenting rejections must be withdrawn because they are not based upon a proper analysis of the claims of the allegedly offending patent or application in combination with the teachings of the prior art.

A. A Proper Double Patent Analysis

An obviousness type double patenting analysis requires the comparison of one or more claims of an applicant's earlier patent or patent application with one or more pending application claims to determine if applicant's other patent or application claim(s) along with any cited prior art renders the pending application claims obvious. The specification of the cited commonly owned patents or patent applications may not be used in an obviousness type double patenting rejection as prior art. Instead, the examiner may only resort to the specifications of the commonly owned patents and application in order to understand the meaning of terms of any claims cited in the double patenting rejection.

MPEP §804(II)(B)(1) summarizes the factual inquiries that must be made in an obviousness-type double patenting analysis. The inquiries are:

(A) Determine the scope and content of a patent claim relative to a claim in the application at issue;

(B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim of the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

Id. (emphasis added). Thus the proper double patenting analysis requires the comparison of the claim(s) of a patent application with claims of another patent or patent application owned by the same Applicant.

B. The Examiner Has Improperly Based The Double Patent Rejections On What The Alleged Conflicting Specifications Teach

The examiner's obviousness-type double patent rejections are flawed because they each compare what is taught in the specification of an allegedly conflicting patent or patent application with what is being claimed in the current application. For example, the examiner's analysis of Applicant's co-pending application 10/629,368 for double patenting is reproduced below.

> Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-11*** of copending Application No. **11/253,322** in view of **Swinyard et al. (II)** (PTO-892 ref. **S**) and further in view of **Harvey** (PTO-892 ref. **T**).
>
> In the portion of the **'322** application at pages 8-9, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.
>
> The **'322** reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.
>
> The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.
>
> In light of the generic teaching of "buffered" CVT-3146 compositions in the **'322'** application and the teachjings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the **'322** application in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

Notably, there is absolutely no comparison of the scope and content of the claims of the present application or the scope and content of the '322 application claims and there is no attempt to indentify differences between the claims as the double patenting test requires. This same

analysis defect is present in all of the examiner's double patenting rejections. For this reason, every obviousness-type double patenting rejection must with withdrawn.

C. There Is No Double Patenting

Following a proper analysis, the examiner must conclude that there is no double patenting. The present application includes claims directed to a pharmaceutical composition and methods for its administration where the composition includes the compound CVT-3146 and certain specific pharmaceutical excipients. The claimed pharmaceutical excipients are (1) sodium phosphate; (2) propylene glycol; and (3) EDTA.

1. The '322 Application Claims

The examiner rejected claims 74, 77 and 79-89 for obviousness-type double patenting in view of claims 1-11 of Applicant's co-pending application no. 11/253,322. Claim 1 of the '322 application is directed generally to a method of producing coronary vasodilatation with little peripheral vasodilatation comprising administering to a human a single intravenous (iv) bolus dose of a pharmaceutical composition comprising regadenoson (CVT-3146) and at least one pharmaceutical excipient. No specific excipients are claimed. The examiner is reminded that the specification may be consulted to construe the term "excipient" but it cannot be construed to read certain excipients – such as buffers – into the claims. As a result, one dramatic difference between the pending claims and the claims of the '322 application is the claiming of a pharmaceutical composition including specific pharmaceutical excipients in the present application.

As the Examiner is aware, to establish *prima facie* obviousness, two basic criteria must be met. First, there must be some suggestion or motivation to combine the teachings of different references – in this case, the prior art application claims with Swinyard et al. Second, there must be a reasonable likelihood of success in light of the prior art. *Brown & Williamson Tobacco Corp. v. Phillip Morris Inc.* 229 F.3d 1120, 56 USPQ2d 1456, 1459 (2000) citing *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The use of the specific claimed excipients in a pharmaceutical composition including CVT-3146 is not obvious. There are literally thousands of ingredients that may be used in

pharmaceutical excipients in pharmaceutical composition formulations. Indeed, the Swinyard reference must disclose hundreds of possible excipients. The evaluation of each possible Swinyard excipient for efficacy with CVT-3146 would be a daunting task that would require undue experimentation. Indeed, the preparation of a pharmaceutical formulation is often a trial and error process and the choice of excipients is not necessarily obvious or readily apparent based upon the pharmaceutical composition itself nor upon the desired administration method. The Swinyard reference discloses a plethora of pharmaceutical excipients. The selection of the three claimed excipients from the vast number of excipients disclosed in Swinyard in view of the claims of the '322 application would clearly not be obvious to one skilled in the art at the time of the invention. As a result the all pending application claims are patentable over the claims of the '322 application.

2. The '368 Application Claims

The examiner rejected claims 74, 77 and 79-89 for obviousness-type double patenting in view of claims 1-4, 6-18 and 21-30 of Applicant's co-pending application no. 10/629,368. All '368 application claims are directed to methods for administering the compound identified as CVT-3146. No other compounds or pharmaceutical excipients are claimed. The present application claims are not obvious over claims of the '368 application for at least the same reasons recited in section I(C)(1) above.

3. The '768 Application Claims

The examiner rejected claims 74, 77 and 79-89 for obviousness-type double patenting over allowed claims 11, 14-27, 29-30, 34 and 36-37 of application no. 11/070,768. The '768 application claims are directed to methods for administering compounds identified as CVT-3146 and CVT-3033. Several of the claims require the compound to be formulated into a liquid. Otherwise the claims are silent about incorporating the compounds into a pharmaceutical composition that includes pharmaceutical excipients. The present application claims are not obvious over claims of the '768 application for at least the same reasons recited in section I(C)(1) above.

4. U.S. Patent No. 7,183,264

Claims 74, 77 and 79-89 stand rejected for obviousness-type double patenting over claims 5-8 and 10-22 of the '264 patent. The '264 patent claims are directed generally to methods of administering and to pharmaceutical compositions including the compound identified

as CVT-3146. Only three of the '264 patent claims are directed to aspects of a pharmaceutical composition. Claim 3 calls for CVT-3146 to be combined with "one or more pharmaceutical excipients." Claim 4 calls for the pharmaceutical composition to be in the form of a solution. Claim 9 calls for the compound to be formulated for injection. None of the '264 patent claims identifies any specific useful pharmaceutical excipients nor do the claims suggest any useful excipients. The present application claims are not obvious over claims of the '264 patent for at least the same reasons recited in section I(C)(1) above.

5. U.S. Patent No. 7,144,872

The examiner rejected claims 74, 77 and 79-89 for obviousness-type double patenting over claims 10-24 of the '872 patent. Claims 10-24 of the '872 patent are directed to method for using the compounds of claims 1. Claims 10-24 do not call for any pharmaceutical ingredients other than the active compound. Therefore in would not be obvious based on the cited '872 patent claims to consider pharmaceutical excipients at all. Moreover, the present application claims are not obvious over claims of the '872 patent for at least the same reasons recited in section I(C)(1) above.

6. U.S. Patent No. 6,642,210

The examiner rejected claims 74, 77 and 79-89 for being obvious over claims 9-11 and 16 of the '210 patent. Claim 9 of the '210 is directed to a method of stimulating coronary vasodilatation in a mammal comprising administering by intravenous bolus injection an amount of a compound of claim 1 that is sufficient to stress the heart and induce a coronary steal situation for the purposes of imaging the heart. Claim 10 requires the mammal to be a human. Claim 11 requires the compound to be combined with at least one pharmaceutical excipient. Claim 16 is directed to dilating the coronary vessels of a mammal, as an adjunct to angioplasty, with the pharmaceutical composition of claim 11. None of the '210 patent claims identifies any specific useful pharmaceutical excipients nor do the claims suggest any useful excipients. The present application claims are, therefore, not obvious over the cited claims of the '210 patent for at least the same reasons recited in section I(C)(1) above.

7. U.S. Patent No. 6,403,567

The examiner rejected claims 74, 77 and 79-89 for being obvious over claims 9-13 of the '567 patent. Claim 9 of the '567 patent is directed to 9 a method for stimulating coronary vasodilatation in a mammal by administering by intravenous bolus injection an amount of a

compound of claim 1 – which includes CVT-3146. Claim 10 requires the mammal to be a human. Claim 11 is directed to a pharmaceutical including a compound of claim 1 and one or more pharmaceutical excipients. Claim 12 requires a pharmaceutical composition is in the form of a solution. Claim 13 is directed to CVT-3146. None of the '567 patent claims identifies any specific useful pharmaceutical excipients nor do the claims suggest any useful excipients. The present application claims are, therefore, not obvious over the cited claims of the '567 patent for at least the same reasons recited in section I(C)(1) above.

8. The '834 Application

The examiner rejected claims 74, 77 and 79-89 for being obvious over claims 26-44 of application no. 11/588,834. Claim 26 is directed generally to a class of compounds that includes CVT-3146. Only claims 42-44 related to pharmaceutical compositions. Claim 42 is directed to the compound of claim 26 including "at least one pharmaceutical excipient." Claim 43 requires the pharmaceutical composition to be in the form of a solution. Claim 44 requires the pharmaceutical composition to be formulated for injection. None of the '834 application claims identifies any specific useful pharmaceutical excipients nor do the claims suggest any useful excipients. The present application claims are, therefore, not obvious over the cited claims of the '834 application for at least the same reasons recited in section I(C)(1) above.

II. THE ALLEGED CONFLICTING CLAIMS

The examiner has taken the position that claims 74, 77 and 79-89 of this application conflict under 37 CFR §1.78(b) with claims of co-pending patent application nos. 10/629,368; 11/070,768; 11/253,322; and 11/588,834 and that the elimination of such claims from all but one application may be required in the absence of good and sufficient reasons for their retention during pendency in more that one application. The examiner goes on to require the Applicant to cancel the conflicting claims or to maintain a clear line of demarcation between the applications.

As an initial matter, the Applicant disagrees with the examiner's position that the applications include "conflicting claims." None of the claims are identical, and all of the claims of the different applications are patentably distinct from one another. In addition, the Applicant intends to maintain a clear line of demarcation between the applications and their claims. For at least these reasons, the examiner's position that the applications include "conflicting claims" is traversed.

CONCLUSION

The examiner's claim rejections are traversed above. Favorable reconsideration and allowance of all pending application claims is courteously solicited.

Should the Examiner have any questions, he is invited to contact the undersigned attorney at (312) 913-2123.

Respectfully submitted,

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